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TITLE:	Delivery Devices and Methods of Delivering Liquids and Nutrition to Patients
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DELIVERY DEVICES AND METHODS OF DELIVERING LIQUIDS AND NUTRITION TO PATIENTS

FIELD OF THE INVENTION

[0001] The present invention relates to delivery devices for delivering liquids to patients and, more particularly, to enteral feeding tubes for delivering nutrition to patients via the nose and/or via abdominal openings.

BACKGROUND

[0002] Enteral feeding refers to methods of providing nutrition through a tube directly into the stomach and/or small intestine of a patient. Such methods are frequently the primary or exclusive source of nutrition for patients who cannot safely ingest for any reason sufficient quantities of food to satisfy their caloric requirements. Candidates for enteral feeding include: premature babies, infants, children, and others having limited or compromised esophageal strength/control; the chronically and/or terminally ill; stroke victims; comatose patients; burn victims; cancer patients; those inflicted with Alzheimer's disease; post-operative patients; patients requiring mechanical ventilation; the weak or infirm; and the like.

[0003] Typically, enteral feeding devices are inserted into patients through the nose or through an opening in the abdominal wall (e.g., gastrostomies) into the stomach. From this point, feeding may be initiated either pre-pylorically into the stomach (i.e., when the end of the feeding device does not extend past the pyloric valve) or post-pylorically (i.e., when the end of the feeding device extends past the pyloric valve into a region of the small intestine).

[0004] Pre-pyloric (intragastric) enteral feeding has the requirement for gastric emptying to deliver nutrients into the small intestine where digestion and absorption takes place. Failed or delayed gastric emptying results in retention of nutrient solution in the stomach, from which it can be regurgitated back into the esophagus. Many of the same patients who require tube feeding due to their inability to eat also have poor gastric function and, therefore, are at risk of esophageal regurgitation and the associated risk of

tracheobronchial aspiration. This risk may be reduced using post-pyloric (small bowel) placement of the enteral feeding tube. However, to effect post-pyloric intubation, it is necessary to maneuver the tip of the enteral feeding tube through the pylorus and into the duodenum. Two general approaches have been taken to accomplish this. The one most commonly employed at present is to visually guide the tube, which is often stiffened with an internal wire, through the pylorus using endoscopy or fluoroscopy x-ray techniques. Such methods are inconvenient, costly, and potentially dangerous. Another approach has been to rely on the gastric motility to pass the tube into the small intestine. Tubes currently in use that purport to facilitate passage from the stomach rely on applying weighted tips to flexible tubes. The weights used vary according to design and have included mercury, lead, and tungsten. These tubes have not proven to be effective devices for directing feeding tubes into the small intestine because weight is not functionally important in intestinal passage with the exception of in the esophagus when eating in an upright position. For these reasons, it would be advantageous to develop methods and feeding devices that bypass the use of weighted metal tips and which rely instead on the natural peristaltic motion of the stomach to safely transport the end of a feeding tube through the pylorus and into the small intestine.

SUMMARY

[0005] The scope of the present invention is defined solely by the appended claims, and is not affected to any degree by the statements within this summary.

[0006] By way of introduction, a first delivery device embodying features of the present invention includes (a) a catheter having a first end and a second end; and (b) an expandable, digestible member connected to the first end of the catheter.

[0007] A second delivery device embodying features of the present invention includes (a) a substantially flexible catheter having a first end and a second end, wherein the catheter contains a biocompatible polymer; and (b)

an expandable, digestible member connected to the first end of the catheter, which is substantially dehydrated in a collapsed state, and which swells upon contact with gastric juices.

[0008] A method of delivering a liquid to a patient includes (a) intubating the patient with a delivery device containing a catheter having a first end and a second end; and an expandable, digestible member connected to the first end of the catheter; and (b) delivering the liquid through the catheter into the patient.

[0009] A method of delivering nutrition to a patient includes (a) intubating the patient through a nasal opening with a delivery device containing a substantially flexible catheter having a first end and a second end, wherein the catheter contains a biocompatible polymer; and an expandable, digestible member connected to the first end of the catheter, which is substantially dehydrated in a collapsed state, and which swells upon contact with gastric juices, wherein intubating continues until the first end of the catheter reaches the interior of the stomach of the patient; (b) contacting the expandable, digestible member with gastric juices in the stomach, such that the expandable, digestible member is converted from the collapsed state to a swelled state; (c) moving at least a portion of the first end of the catheter through the pylorus of the patient by peristaltic action of the stomach upon the expandable, digestible member; and (d) delivering the nutrition through the catheter into a region of small intestine of the patient.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] FIG. 1 shows a perspective view of a first delivery device embodying features of the present invention, which depicts a first expandable, digestible member in accordance with the present invention.

[0011] FIG. 2 shows a cross-sectional view of a second expandable, digestible member in accordance with the present invention.

[0012] FIG. 3 shows a cross-sectional view of a third expandable, digestible member in accordance with the present invention.

[0013] FIG. 4 shows a detailed view of a fourth expandable, digestible member in accordance with the present invention.

[0014] FIG. 5 shows a perspective view of a fifth expandable, digestible member in accordance with the present invention.

[0015] FIG. 5A shows a perspective view of a sixth expandable, digestible member in accordance with the present invention prior to insertion in a patient.

[0016] FIG. 5B shows the expandable, digestible member of FIG. 5A in an expanded, hydrated state.

[0017] FIG. 6 shows a partial cross-sectional view of a sixth expandable, digestible member in accordance with the present invention.

[0018] FIG. 7 shows a perspective view of a second delivery device embodying features of the present invention.

[0019] FIG. 8 shows a perspective view of a third delivery device embodying features of the present invention.

[0020] FIG. 9 shows an illustration of a nasoenteric feeding tube embodying features of the present invention intubated in a patient prior to passage of the tube through the pylorus and prior to degeneration of the erodable coating surrounding the expandable, digestible member.

[0021] FIG. 10 shows an illustration of the nasoenteric feeding tube of FIG. 9 after degeneration of the erodable coating and subsequent swelling of the expandable, digestible member but prior to passage of the tube through the pylorus.

[0022] FIG. 11 shows an illustration of the nasoenteric feeding tube of FIGS. 9 and 10 after peristaltic transportation of the expandable, digestion member through the pylorus and prior to full digestion of the expandable, digestible member.

DETAILED DESCRIPTION

[0023] Delivery devices and methods suitable for delivering liquids and/or nutrients directly into the small intestine of a patient, either through a nasal opening or an abdominal opening, have been discovered which circumvent

the above-mentioned problems. The devices contain (a) a catheter having a first end and a second end, and (b) an expandable, digestible member annealed to the first end of the catheter. The expandable, digestible member, which is in a collapsed state when the patient is initially intubated, functions in a manner analogous to conventional tungsten or silicon weighted tips by helping to guide the tube to its destination, albeit by relying on tractable hydrated mass or volume. It is well established that a small length of yarn connected to a length of string will quickly pass from the stomach into the small intestine, which is the basis of the "sting test" method for collecting small intestinal juices for diagnostic analysis. The above-described tube design relies on a similar principle. By annealing a swelling biopolymer to the first end of a small caliber and highly flexible feeding tube, yarn on the end of a length of string may be emulated. Upon contacting the gastric juices of the stomach, the expandable, digestible member swells. Once swollen, the expandable, digestible member may be engaged and transported by the natural peristaltic motion of the stomach through the pylorus and into the small intestine. However, it would be disadvantageous for the tractable member to remain in place after the tip of the tube has reached its desired position because the intestinal motility would continue to tug on it, which would be uncomfortable to the patient and could result in dangerous consequences. Therefore, designs in accordance with the present invention include the use of a digestible biopolymer as the swelling member. The expandable, digestible member is digested (e.g., in the small intestine) and gradually decreases in size. When the expandable, digestible member is completely digested or at least sufficiently reduced in size, peristaltic transportation of the catheter through the body ceases and enteral feeding through the catheter can be initiated.

[0024] Throughout this description and in the appended claims, the following definitions are to be understood:

[0025] The phrases "connected to" and "annealed to" refer to all manner of contact between two adjacent elements. The connection may be a physical or chemical bond (e.g., such as would be provided by sulfhydryl bond

formation, adhesives, etc.) between two elements made of different materials (e.g., an expandable, digestible member and a first end of the catheter). Alternatively, the connection may be a physical or chemical bond between two structurally contiguous elements formed of the same material (e.g., the first end and remaining portions of the catheter and a flexible linker intermediate therebetween, such as are described below).

[0026] The phrase "substantially dehydrated" refers to any state in which the moisture that would normally be present in a material under ambient conditions is no more than about 10% of the moisture the substance would acquire if submerged for a period in water.

[0027] The term "fibrous" refers to a thread-like texture.

[0028] The phrase "collapsed state" refers to the state of an expandable, digestible member that is substantially dehydrated.

[0029] The term "swelled" and the phrase "swelled state" refer to the state of an expandable, digestible member that has increased in size relative to a collapsed state through contact with the contents (e.g., gastric juices) of a stomach.

[0030] The term "liquid" refers to any fluid substance including but not limited to pure substances (e.g., water), homogeneous solutions containing one or a plurality of solutes dissolved therein, heterogeneous suspensions, emulsions or multi-phase mixtures, and the like.

[0031] The term "intubating" refers to insertion of any portion of a delivery device embodying features of the present invention into any suitable orifice of a patient. Suitable orifices include but are not limited to the nose and abdominal openings.

[0032] The phrase "proximal small intestine" refers to any region in the first one third of the length of the small intestine and includes the duodenum, which is the first region of the small intestine located between the stomach and the jejunum.

[0033] A first series of presently preferred delivery devices embodying features of the present invention is shown in FIGS 1-6. The delivery device **2** includes (a) a catheter **4** having a first end **6** and a second end **8**; and (b) an

expandable, digestible member **10** connected to the first end **6** of the catheter **4**.

[0034] The catheter **4** may be flexible or rigid and may be manufactured from any biocompatible material including but not limited to polymers, metals, and a combination thereof. It is presently preferred that the catheter be flexible and that that the catheter be comprised of a polymer, more preferably, a biocompatible thermoplastic polymer. Representative biocompatible polymers for use in accordance with the present invention include but are not limited to polytetrafluoroethylene, polyurethane, silicone, and the like, and combinations thereof. While the type of material, dimensions (e.g., length, internal and external diameters, etc.) and degree of flexibility of a catheter used in accordance with the present invention are not limited, it is presently preferred that the catheter be sufficiently slender, flexible, and resilient to be useful for nasoenteric applications.

[0035] It is to be understood that catheters in accordance with the present invention may vary considerably with respect to their design. For example, depending on a given application (e.g., whether the tube is a nasoenteral tube or a jejunostomie tube), catheters may vary in length; thickness; interior bore size; external markings (e.g., tubes may be marked with reference distances to assist in intubating a patient); number, shape (e.g., circular, elliptical, etc.), and location of openings in the catheter through which materials may pass from an interior to an exterior thereof or vice versa; type of connector attached at the end of the catheter opposite to the end inserted in the patient; and so forth.

[0036] The expandable, digestible member **10** is substantially dehydrated when in a collapsed state but swells upon contact with gastric juices. The duration of contact with gastric juices required to achieve full swelling of the expandable, digestible member **10** may vary according to the nature of the expandable, digestible member **10**, the type of weave and of texture thereof, the content and/or acidity of an individual's stomach, and the like. Preferably, full swelling occurs within about 5 minutes of introducing the exposed expandable, digestible member **10** into a stomach, and more preferably within

about 3 minutes. In addition, it is preferred that the expandable, digestible member be substantially fibrous. Suitable materials for use as expandable, digestible members in accordance with the present invention include but are not limited to protein collagens (e.g., extracted from cowhide) and carbohydrate polymers (e.g. plant fiber).

[0037] Preferably, an external diameter **20** of the expandable, digestible member **10** in a collapsed state does not exceed an external diameter **22** of the catheter **4** by more than about twenty percent, more preferably by more than about ten percent. Furthermore, an external diameter **24** of the expandable, digestible member **10** in a swelled state does exceed an external diameter **22** of the catheter **4** by more than about fifty percent, more preferably by more than about two hundred percent.

[0038] It is to be understood that expandable, digestible members embodying features of the present invention may vary considerably with respect to their size and shape both in the collapsed state and in the swelled state. Strictly by way of illustration, the expandable, digestible member may have any regular or irregular geometric shape including but not limited to: spherical, hemispherical, obround, tetrahedral, cubic, cuboidic, pyramidal, frusto-pyramidal, cylindrical, frustoconical, ellipsoidal, oblate spheroidal, prolate spheroidal, catenoidal, and the like. Likewise, it is to be understood that the general shape of the expandable, digestible member may or may not be retained during the transformation from collapsed state to swelled state. Indeed, it is expected that the material will string out from the first end of the feeding tube in a manner similar to yarn.

[0039] All manner of configurations and all manner of connection means have been contemplated for joining the expandable, digestible member **10** to the first end **6** of the catheter **4**. FIGS. 1-5 depict alternative types of configurations that may be used in accordance with the present invention.

[0040] FIG. 1 shows a first embodiment of an expandable, digestible member **10** embodying features of the present invention, whereby the expandable, digestible member **10** contacts only an external edge surface **12** of the first end **6** of catheter **4**.

[0041] FIG. 2 shows a second embodiment of an expandable, digestible member **10** embodying features of the present invention, whereby the expandable, digestible member **10** contacts only an external side surface **14** of the first end **6** of catheter **4**.

[0042] FIG. 3 shows a third embodiment of an expandable, digestible member **10** embodying features of the present invention, whereby the expandable, digestible member **10** contacts an external edge surface **12** and an external side surface **14** of the first end **6** of catheter **4**.

[0043] FIG. 4 shows a fourth embodiment of an expandable, digestible member **10** embodying features of the present invention, whereby the expandable, digestible member **10** contacts an internal side surface **16** of the first end **6** of catheter **4**.

[0044] FIG. 5 shows a fifth embodiment of an expandable, digestible member **10** embodying features of the present invention, whereby an external side surface **14** of the first end **6** of catheter **4** defines a plurality of perforations **18**, wherein the expandable, digestible member **10** is secured to the first end **6** by being woven through and/or tied to perforations **18**.

[0045] FIG. 5A shows a sixth embodiment of an expandable, digestible member **10** embodying features of the present invention in which a plurality of strands of the material are anchored to and wrapped around the sides of catheter **4** (e.g., via sulfhydryl bond formation) prior to insertion in a patient. FIG. 5B shows the expandable, digestible member **10** of FIG. 5A in an expanded, hydrated state, wherein the strands of the material have become unwrapped and extend downward into the patient to form a substantially flame-shaped mass. In a first presently preferred embodiment, the length of the strands is between about 3 and about 4 centimeters, although it is to be understood that additional lengths may be used and the ratio of the length of the strands to the tube size may be optimized for best traction.

[0046] A presently preferred technique for attaching the expandable, digestible member **10** to the catheter **4** is through the use of a biocompatible adhesive, such as is know to those of ordinary skill in this art. Representative

biocompatible adhesives that may be used in accordance with the present invention include but are not limited to fluorinated ethylene propylene.

[0047] Other arrangements whereby the expandable, digestible member **10** can be secured to the first end **6** of catheter **4** can be used in accordance with the claimed invention. For example, the expandable, digestible member **10** can be taped to the external side surface **14** with a biocompatible adhesive tape. Alternatively, the external side surface **14** may contain one or more crimped surfaces whereby a portion of an expandable, digestible member **10** is retained. Alternatively, when the catheter is comprised of a metal, an electrodeposition technique for deposition of collagen materials (e.g., such as is described in U.S. Patent No. 6,391,052) may be employed.

[0048] Delivery devices embodying features of the present invention preferably contain an optional erodable coating **26**, as shown in FIG. 6, that surrounds at least a portion of, more preferably the entirety of, the expandable, digestible member **10**. The erodable coating **26** degenerates upon contacting contents of a stomach and functions to prevent premature swelling of the expandable, digestible member **10** during intubation of a patient. Premature swelling refers to swelling that occurs prior to the arrival of first end **6** in the interior region of a patient's stomach. Suitable materials for use as erodable coatings in accordance with the present invention include water soluble coatings (e.g., sugar-based materials), gelatin, and the like. Optionally, the erodable coating **26** may contain a topical analgesic such that irritation caused by contact between an interior surface of a patient and a portion of the delivery device being inserted may be alleviated.

[0049] The second end **8** of catheter **4** may be fitted with a connector **28** of a type known in the art (e.g., see U.S. Patent No. 4,781,704: col. 3, line 59 to col. 4, line 17) and shown in FIG. 1, whereby nutrient-containing liquids can be introduced into enteral feeding tubes. The connector **28** may contain one or a plurality of ports **30**, at least one of which is preferably a female-type adapter. Connectors containing two ports are preferably arranged in a Y-shaped configuration, as shown in FIG. 1. Connectors containing three ports

are preferably arranged in a W-shaped configuration (not shown). When ports **30** are not in use, they may be closed off with caps **31**.

[0050] A second series of presently preferred delivery devices embodying features of the present invention is shown in FIG 7. The delivery device **32** includes a first expandable, digestible member **34** located at the first end **36** of a catheter **38** as well as a second expandable, digestible member **40** connected to an external surface **42** of catheter **38** at a region **44** interposed between the first end **36** and second end **46** thereof. Such devices provide an additional control mechanism whereby a feeding tube may be intubated to a precise location within a patient. For example, the first expandable, digestible member **34** may be coated with a first erodable coating **48** (not shown) and the second expandable, digestible member **40** may be coated with a second erodable coating **50** (not shown) different from the first erodable coating **48**. The expandable, digestible member coated with the more rapidly degraded erodable coating will be the first to be exposed to the stomach contents and, therefore, the first to swell and be carried by peristaltic movement through the pylorus. Subsequent degradation of the remaining erodable coating will provide a second handle for further peristaltic transportation of the feeding tube deeper into the duodenum of the patient if so desired.

[0051] A third series of presently preferred delivery devices embodying features of the present invention is shown in FIG 8. The delivery device **52** contains a flexible linker **54**, wherein the first end **56** of the catheter **58** is connected to remaining portions **60** thereof through the intermediacy of the flexible linker **54**. The flexible linker **54** preferably exhibits high deformability and flexibility, such that peristaltic movement of the stomach will respond to the first end **56** which contains an erodable, digestible member **62** as if it were a free-floating, independent mass. The principles by which the flexible linker **54** contributes to post-pyloric intubation are set forth in U.S. Patent No. 5,057,091 to Erik Anderson, the entire contents of which are incorporated herein by reference, except that in the event of any inconsistent disclosure or

definition from the present application, the disclosure or definition herein shall be deemed to prevail.

[0052] A first series of presently preferred methods for delivering liquids to a patient include (a) intubating the patient with a delivery device of a type described above, and (b) delivering the liquid through the catheter into the patient. Intubating may be achieved through any suitable orifice and/or surgical opening in a patient, including but not limited to a nasal cavity and an abdominal opening. Preferably, intubating is achieved through the nose or a nasal passage. In addition, it is presently preferred that the liquid be delivered directly into the proximal small intestine of the patient (i.e., post-pylorically).

[0053] FIG. 9 illustrates the first phase of intubating a patient in accordance with the present invention. During this phase, the first end **6** of a catheter **4** is guided to the interior of a patient's stomach **63**. It is preferred that the delivery device **2** initially contain a stylet (or guide wire) **64**, which is removably inserted in the interior bore of catheter **4**, and which can be withdrawn therefrom after the first end **6** has been properly positioned.

[0054] FIG. 10 illustrates the second phase of intubating a patient in accordance with the present invention. During this phase, the erodable coating **26** has been degenerated such that the expandable, digestible member **10** contacts the gastric juices in the stomach and is converted from the collapsed state to the swelled state. As shown in FIG. 10, the hydrated and expanded mass of biomaterial **10** is substantially flame-shaped with a bulky body and a longish tail trailing off into the intestine.

[0055] FIG. 11 illustrates the third phase of intubating a patient in accordance with the present invention. During this phase, the swelled expandable, digestible member **10** has been transported by the agency of the peristaltic contractions of the stomach, such that at least a portion of the first end **6** of catheter **4** extends past the pylorus **66** of the patient.

[0056] During the final phase of intubation (not shown), expandable, digestible member **10** is gradually digested until an insufficient quantity remains to continue the peristaltic transportation of the catheter **4**. In general,

traction of the catheter **4** is proportional to the amount of expandable, digestible member **10** that remains undigested.

[0057] Although the liquid delivered to patients by delivery devices embodying features of the present invention has been described primarily in reference to enteral feeding and nutrient delivery, it is to be understood that all manner of materials suitable for internal administration to a patient have been contemplated for use in accordance with the present invention. Suitable materials include but are not limited to nutrient solutions, antibiotics, saline solution, analgesics, antiviral agents, antimicrobials, antifungals, anti-tumor drugs, anti-inflammatory agents, antihelmintics, and the like, and combinations thereof.

[0058] The foregoing detailed description and accompanying drawings have been provided by way of explanation and illustration, and are not intended to limit the scope of the appended claims. Many variations in the presently preferred embodiments illustrated herein will be obvious to one of ordinary skill in the art, and remain within the scope of the appended claims and their equivalents.